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| 10/593,504 | 09/20/2006 | Robert M. Garbaccio | 21607P | 9392 |
| 210 7590 01/21/2009 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907 | | | | |
| EXAMINER | | | | |
| BROOKS, CLINTON ALAN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 4121 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,504

Applicant(s)

GARBACCIO ET AL.

Examiner

CLINTON BROOKS

Art Unit

4121

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8 and 9 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 5, 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-854/IC)
Paper No(s)/Mail Date See Continuation Sheet

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/12/2007, 4/09/2008, 10/17/2008.

DETAILED ACTION

This application is a §371 application of PCT/US2005/009198 that was filed on March 18, 2005, which claims priority from U.S. Provisional Application No. 60/555,164, filed on March 22, 2004.

Claims 1-9 are pending.

Election/Restriction

Applicant's election without traverse of the species: N-2-(3-chloro-4-fluorophenyl)-N-1-[2-(dimethylamino)ethyl]-N-2-(3-hydroxybenzyl)alaninamide in the reply received on October 31, 2008 is acknowledged. The election is deemed proper and is therefore made FINAL.

No art was identified on the elected specie: N-2-(3-chloro-4-fluorophenyl)-N-1-[2-(dimethylamino)ethyl]-N-2-(3-hydroxybenzyl)alaninamide. After searching the structures of Claims 6 and 7 using STN and applying the searches disclosed in the search notes, Examiner found no anticipating or obvious variants of the compounds recited in Claims 6 and 7.

Objections

1. Claims 3-5, 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

• Claim Rejections - 35 USC § 112, second paragraph/101

2. 35 U.S.C. 101 reads as follows:

3. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 9 provides for the use of the compound according to Claim 1 for the preparation of a medicament useful in the treatment or prevention of cancer in a mammal in need of such treatment, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
6. Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,2, and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fox *et al.* (J. Org. Chem., Vol. 38 , No. 6, 1973, p. 1136-1140, "the Fox article", provided by Applicant in the IDS received 2/12/2007).

8. Regarding Claims 1, 2, and 8, the Fox article teaches a compound of Formula I. Specifically, Table V of the Fox article teaches a compound (registry no. 37931-54-7) where X = H, and Y = F.

9. Regarding Claim 8, the experimental procedure of the Fox article teaches the synthesis of the compounds in Table 5. In addition, those compounds are dispersed in a pharmaceutical carrier--an ethereal solvent. The compounds are synthesized starting at a 2.4 mmol scale and yields of 30-73% (experimental section) are obtained, giving an ethereal solution containing more than an effective amount. For example, the specification of the instant application discloses: "a suitable amount of compound is administered to a mammal undergoing treatment for cancer. Administration occurs in an amount between about 0.1 mg/kg of body weight to about 60 mg/kg of body weight per day[.]" (instant application, US2008/0234281, paragraph 143).

Conclusion

10. Claims 1, 2, 8, and 9 are rejected. Claims 3-5 and 7 are objected and Claims 6 is deemed allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON BROOKS whose telephone number is (571)270-7682. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:00 PM EST.
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PATRICK NOLAN can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cab

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121